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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/411,797	10/01/1999	STEVE A. HERWECK	ATA-257	8813

959 7590 09/24/2003

LAHIVE & COCKFIELD  
28 STATE STREET  
BOSTON, MA 02109

EXAMINER
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LAM, ANN Y

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 09/24/2003

23

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Applicati n N .

09/411,797

Applicant(s)

HERWECK ET AL.

Examiner

Ann Y. Lam

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 June 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-27 and 44-52 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 45-49 is/are allowed.
- 6) ☒ Claim(s) 1,2,4-27,44 and 50-52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 22.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4-27, 44 and 50-52 are rejected under 35 U.S.C. 102(e) as being anticipated by Bodicky, 5,269,755.

As to claims 1, 6-9, 13, 14, 25 and 50, Bodicky discloses a member (40) constructed of a biocompatible material, the member having a longitudinal axis and a wall having a thickness extending between an inner and an outer surface, the wall having a microstructure of nodes (C) interconnected by fibrils (D), the member being deployable from a first, reduced diameter configuration to a second, increased diameter configuration, see column 5, lines 23-27, wherein the wall of the member includes at least one microporous portion of micro-channels (E) formed by microstructure having a porosity sufficient for a fluid to expand the fluid delivery device and permeate through micro-channels substantially controlling the permeation of fluid through the wall, see column 5, lines 23-30, and lines 61-65.

As to claim 2, the material is ePTFE, see column 5, line 8.

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As to claim 4, the member has a hydrophobic exterior surface.

As to claim 5, the internodal distance is 1  $\mu\text{m}$  – 150  $\mu\text{m}$ , see column 5, lines 35-36.

As to claim 10, the size of the micro-channels varies circumferentially, see column 5, lines 23-27.

As to claim 11, the member deploys to the second configuration upon application of a fluid having a pressure of approximately 1 psi to 250 psi, see column 5, lines 23-27.

As to claim 12, porosity is sufficient to allow fluid to pass therethrough at a flow rate of approximately 0.01 ml/min to 100 ml/min, see column 5, lines 23-27.

As to claim 15, the medicinal agent is antibiotics, see column 6, line 4 .

As to claim 16, the microporous portion of the wall borders a second portion of the wall that is generally impermeable, (distal end of member 40, see column 6, lines 51-56.)

As to claims 17, the wall further includes a second microporous portion (e.g., distal portion of 40) having a porosity sufficient for the fluid to permeate through the wall.

As to claim 19, the second microporous portion is considered to be spaced apart longitudinally from a first microporous portion.

As to claim 20, the second microporous portion (ie.g., distal portion of 40) is considered to be spaced circumferentially from a first microporous portion.

As to claim 27, the size of the micro-channels varies circumferentially about the member, see column 5, lines 23-27.

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As to claim 44, the nodes (C) are substantially perpendicular to the longitudinal axis of the balloon.

As to claim 18, an impermeable portion of the wall (C) is considered interposed between the microporous portion and the second microporous portion.

As to claim 24, the microporous portion is considered to have a hydraulic conductivity less than the hydraulic conductivity of the body vessel.

As to claims 25-27 and 44, the member is constructed of fluoropolymer material, see column 4, lines 66-67.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21-23, and 51-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bodicky, 5,269,755.

Bodicky discloses the invention substantially as claimed, see above, except for the hydraulic conductivity as claimed. However, Bodicky teaches that the pore sizes, and thus, the flow of fluid through the pores, varies according to the stretch of the fibrils (D), and that ePTFE material is chosen to have pore sizes appropriate to allow the desired medicament or other liquid to pass therethrough, see column 5, lines 23-31. Thus, it would have been obvious to chose a particular ePTFE material with the

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hydraulic conductivity as claimed, as would be desirable to have the pore size to allow the desired medicament to pass through.

### ***Response to Arguments***

Applicant's arguments with respect to the above claims have been considered but are moot in view of the new ground(s) of rejection.

### ***Allowable Subject Matter***

Claims 45-49 are allowed.

Claim 3 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: the combination of elements including a first layer of material formed of a microstructure of nodes interconnected by fibrils, and a second layer formed of nodes interconnected by fibrils, the second layer overlying the first layer, wherein fluid permeates from the inner surface of the first layer to the outer surface of the second layer, was not found in the prior art search.

Also, a member formed of a microstructure of nodes and fibrils, the member being porous and having a hydrophilic exterior surface, was not found in the prior art search.

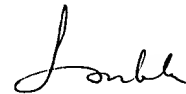
**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is (703) 306-5560. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703)305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

A.L.



LONG V. LE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

09/24/03